

claims as filed. For example, see claims 3 and 4, as filed, as well as page 34, lines 7-8 and page 90, lines 33-34.

#### The Title and Specification

Applicants are hereby amending the title of the invention in accordance with the Examiner's suggestion. Applicants note the Examiner's requirement to review for spelling, TRADEMARKS, and like errors in the specification, as well as to identify the nucleotide and amino acid sequences in the specification with SEQ ID NOS. Such review and corrections will be made when allowable subject matter has been agreed upon, if not sooner.

#### The §112 Rejections

The Examiner has rejected Claims 2-4 and 6 under 35 U.S.C. §112, second paragraph as allegedly being indefinite in the use of the terms "substantial" or "substantially" because the metes and bounds of these terms are allegedly ambiguous and not clearly defined. Applicants respectfully traverse these rejections. The invention involves biochemical reactions (e.g. antibody mediated blockade of complement activity), which, by their nature, and as understood by those of skill in the art, do not involve absolute changes, but rather involve equilibrium reactions which typically result in some residual levels of unaltered reactants being present after the reaction has taken place. Thus, the effects of such reactions are never complete and total, as some residual activity of the unaltered reactants may, at least theoretically, always be measurable if sensitive enough assays are employed. In this light, applicants believe that their use of the term substantially is neither vague nor indefinite. Indeed, use of terms such as "substantially" has been found to be an improper basis for rejection under 35 U.S.C. §112, second paragraph.

In In re Mattison, 509 F.2d 563, 184 USPQ 484 (CCPA 1975), the board held that a compound claim requiring an electron withdrawing substituent selected and positioned on the aromatic ring "to substantially increase the efficiency of the compound as a copper extractant" failed to satisfy the second paragraph of 35 U.S.C.

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§112. The board said: "How much is a substantial increase? Is it 3%, 30%, 300%, or something else?" Id. at 564, 184 USPQ at 485.

Reading the claims in light of the specification, the Court of Customs and Patent Appeals reversed, saying "[h]ypothesizing whether an increase in efficiency of 3%, 30%, or 300% is necessary for said increase to be classified as substantial is not determinative of the issue of whether the claims satisfy 35 U.S.C. §112, second paragraph." Id. at 565, 184 USPQ at 486. (Footnote omitted.) Rather, the Court found that the determinative question is how the claims would be understood by a worker of ordinary skill in the art reading the claims in light of the specification.

This reasoning was also applied by the CAFC in In re Marosi, Stabenow, and Schwarzmann, 218 USPQ 289 (CAFC 1983).

In view of this settled law, applicants submit that their claims, as previously amended in response to the February 18, 1998 Office Action, satisfy the second paragraph of §112. The Examiner has not shown that a person of ordinary skill in the art would have any difficulty in determining the scope of applicants' claims. In particular, in the context of applicants' entire specification, including the problems addressed, the discussions on page 1, lines 15-24, page 13, second and third full paragraphs, page 29, lines 22-34, page 30, lines 2-7 and 12-18, and page 32, lines 29-33, and the examples (including those illustrating the successful achievement of substantially complete blockade of C5a generation and substantially complete blockade of complement hemolytic activity in human body fluids) such a person would have no difficulty in determining whether or not alterations achieved in accordance with applicants' teachings were substantially equal (see claim 2) or substantially complete (see claim 6).

Applicants believe that the above amendments and discussion fully address the Examiner's concerns regarding the claim language and respectfully request that the Examiner reconsider and withdraw his rejections under §112.

The §102 and §103 Rejections

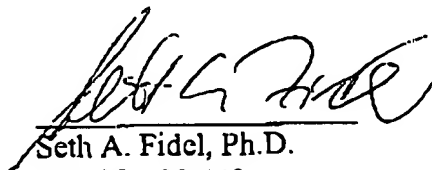
The Examiner has rejected claims 1-12 under §102 and/or §103 over Wurzner et al. (Complement Inflamm. 1991), in some instances in combination with other references. Applicants respectfully traverse these rejections. Applicants' pending claim 1 requires that the antibody be specifically targeted to the alpha chain of human complement component C5. All of applicants' other pending claims depend from claim 1 and share this limitation. As disclosed in Wurzner et al. (Complement Inflamm. 1991) on page 337, first column, first paragraph (continued from previous page) "both anti-C5 mabs are directed against the  $\beta$  chain of C5..."

Thus, Wurzner et al. (Complement Inflamm. 1991) does not anticipate or make obvious the antibodies of applicants' claims. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw his rejections of claims 1-12 under §102 and §103.

**Conclusion**

Applicants respectfully request entry of the above amendments and reconsideration and allowance of claims 1-12.

Respectfully submitted,



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Date: November 4, 1998